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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,240	02/08/2001	Valery Kanevsky	10004226-1	6661

7590 07/02/2004

EXAMINER

AGILENT TECHNOLOGIES
Legal Department, 51U-PD
Intellectual Property Administration
P.O. Box 58043
Santa Clara, CA 95052-8043

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/779,240	KANEVSKY ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 June 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3,7,9-14 and 35-70 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 63-65,69 and 70 is/are allowed.
- 6) Claim(s) 1-3,7,9-14,35-39,45-50,52-62 and 66-68 is/are rejected.
- 7) Claim(s) 40-44, 51 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

Response to After-final Amendment and Arguments

In view of the rejoinder and new rejections of claims 53-70 set forth below, the finality of the previous office action is hereby withdrawn and prosecution is reopened. The amendment filed 6/7/04 has been entered. Claims 1-3, 7, 9-14, and 35-70 are pending. All objections and rejections not reiterated below are hereby withdrawn.

Election/Restrictions

Applicant's arguments filed 6/7/04 with regard to restriction are persuasive, therefore claims 53-70 are considered elected and are rejoined with claims 1-3, 7, 9-14, and 35-52. An action on the merits of claims 1-3, 7, 9-14, and 35-70 follows.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 7, 9-14, 37-39, 46-48, 52, and 58-62, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicant's arguments filed 6/7/04 have been fully considered. Due to a typographical error, the "non-statutory" rejection paragraph and some of the reasons for making a non-statutory-type of rejection were replaced by a "lack of utility" rejection paragraph, and some reasons pertaining thereto, in the previous office action. The examiner apologizes for the error and resulting confusion to applicant. Applicant laudably attempted to address the mixed rejections in the response filed 6/7/04. The arguments have been fully considered but are not persuasive for the reasons set forth below. In order to give applicant an opportunity to fully consider and address the

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corrected rejections, prosecution has been reopened (see above) and this office action made non-final. Applicant's arguments, as they pertain to a rejection for non-statutory subject matter, are addressed below.

As set forth in previous office actions, the method steps recited in the instant claims do not appear to comprise physical manipulation of matter, but appear to be steps equivalent to mental processes

Applicant argues that claims are not required to recite physical manipulation of matter to be statutory and cites MPEP 2106, which states that processes (i.e. recitation of actions) may be permissible subject matter. A method or process which recites physical acts is usually considered statutory; see MPEP 2106.IV.B.2 (b), especially with regard to "safe harbors". The examiner's statements in this regard were intended to clarify the analysis of the claimed invention as one which does not fall within a "safe harbor". Nowhere did the examiner state that a physical step was required, merely that no such steps were recited. In a previous response, applicant had specifically requested that the examiner point to statutory subject matter in the claims. In response to that request, and the obvious confusion over this point, it is noted that specific recitation of active, physical method steps (i.e. outside a computer), while not required, would render the instant claims statutory.

In response to applicant's argument that there is no requirement that a practical application or use be expressly recite in method claims, applicant's attention is directed to MPEP 2106.IV.B.1, which states:

"If the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 USPQ2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of

numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some **claimed practical application** (i.e., executing a “mathematical algorithm”); or
 - simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), **without some claimed practical application.** “

(emphasis added by examiner)

MPEP 2106.IV.B.2 (b) (ii) also states:

“For such subject matter to be statutory, **the claimed process must be limited** to a practical application of the abstract idea or mathematical algorithm in the technological arts. See Alappat, 33 F.3d at 1543, 31 USPQ2d at 1556-57 (quoting Diamond v. Diehr, 450 U.S. at 192, 209 USPQ at 10). See also Alappat 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) (“unpatentability of the principle does not defeat patentability of its practical applications”) (citing O ’Reilly v. Morse, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application **when the method, as claimed**, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See AT &T, 172 F.3d at 1358, 50 USPQ2d at 1452.”

Thus, the MPEP, at least, clearly states that, where a claim does not recite physical acts, it must explicitly recite a concrete, tangible and useful result; i.e. a practical application.

In response to arguments regarding a “concrete, tangible and useful result”, the claimed methods appear to be those of computer processes which merely manipulate data but fail to produce any particular result. In fact, it is unclear what the intended result of any claimed method is actually intended to be. Instant claim 1 recites a preamble of “determining a predictor set of features associated with a target” and ends with a step of “removing at least one feature from the predictor set.” While the resultant “set” is certainly a predictor set, it is unclear what relationship that predictor set actually has with any target, nor what significance or use, if any, may be derived from the subtractive predictor set which results from the method. Applicant argues that the predictor set must be “associated with” a target, as recited in the preamble of claim 1; however, the nature of the “association” of the subtractive predictor set and the target is unknown. It is not clear from the instant claims whether a subtractive predictor set, as would result from the steps of claim 1, is necessarily one which can be used to detect a disease or identify a gene, as argued by applicant. As one skilled in the art would not be able to ascertain what to do with the subtracted predictor set of step (d) of the method of claim 1, the method does not provide a “concrete, tangible and useful” result.

In response to applicant’s previous request that the examiner identify features of the invention which would render the claim statutory, it is noted that the rejected claims do not recite any specific features, target or relationship between a predictor set and target such that the examiner can determine what the actual result of a claimed method is intended to be.

In an attempt to aid applicant in this regard, analysis of specific independent claims is set forth below. Applicant is advised that the analysis includes a comparison of nonrejected and rejected claims; it is hoped that this analysis will help clarify the rejection. Applicant is urged to request an interview if further clarification is needed.

Claim 53, which specifically recites “using” a best predictor set to predict a target, and therefore DOES recite a practical application, is considered statutory. Claim 58, which merely recites steps of adding to and subtracting from a predictor set, with a final step of “incrementing”, but fails to recite any step(s) of detection, identification, etc., is not statutory. Claim 60 recites a step wherein a predictor set is determined as an “optimal predictor set for predicting” a target; however, the ultimate step of claim 60 recites “incrementing” the value of k ; i.e. the last step of the claim is apparently an iterative one, and the claim does not appear to have an endpoint. Claim 61 similarly recites determining an optimal predictor set, followed by an apparently iterative, incrementing step. A method which simply re-iterates its steps in an endless loop does not produce a concrete, tangible and useful result, therefore claims 60 and 61 are not statutory. It is noted that properly rewording and/or re-ordering the steps such that the claims end with a concrete, tangible and useful result (e.g. determination of an optimal predictor set for detecting/identifying a target) may render claims 60 and 61 statutory. See e.g. claims 63 and 65, which are statutory.

Claims 1-3, 7, 9-14, 37-39, 46-48, 52, and 58-62 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Applicant's arguments filed 6/7/04 have been fully considered as they pertain to utility, but they are not persuasive. In response to the argument that the claimed method can be used to identify a gene of interest in a sample, or determine a asset of features associated with a target involved in pharmaceutical or therapeutic utility, it is noted that the rejected claims do not recite any genes or diseases, nor any association with pharmaceuticals or therapy. Instant claim 1 recites a method for “determining” a predictor set of features “associated” with a target, but fails to recite any actual method

steps for determining the “association” nor any definition of the “association”, such that one skilled in the art would be able to “predict”, detect, identify, etc., any target. Further research would be required.

In response to the argument that the claims need not recite a utility, it is noted, as previously set forth, that a utility must be ascertainable without recourse to further experimentation. Applicant is reminded that the results of a method must be of “immediate benefit to the public” (See, e.g., *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 USPQ 689, 695 (1966)) and that a “use” requiring further research is not a utility under 35 USC 101. See MPEP 2107.

As previously set forth and reiterated above, the claimed methods result in a predictor set of features; it is unclear what association, if any, the predictor set has with a target, thus requiring further research . Where the result of the method is unclear (see below) and/or the “association” with a target is not set forth, the claims require further research and do not have utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-36, 45-50, 53-62, and 66-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed 6/7/04 have been fully considered but they are not persuasive.

The term "best" in claims 35, 36, 45, 46, is a relative term which renders the claim indefinite. The term "best" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification defines a "good solution" on page 7 as a set of predictors with "high enough" quality, but does not define the metes and bounds of a "high enough" quality. The specification also defines a "predictor set" on page 6, but does not define a 'best predictor set' anywhere. In response to applicant's argument that one of skill in the art would recognize a "best predictor set" as that set "features associated with a target", it is noted that mere determination of a set of features associated with a target does not appear to be the same as determination of a "best" predictor set or subset. One of skill in the art would not know the metes and bounds intended by applicant for a 'best' predictor set, as recited in the rejected claims, therefore the claims are indefinite. In response to the argument with regard to "assistance" provided by the specification, it is again noted that limitations from the specification can not be read into the claims. Page 11 provides an example, but not a definition, of a best subset of predictor elements. As the definition, or metes and bounds of a "best predictor set" of features may vary, and neither the claims nor specification provide a specific definition, the examiner maintains that the term "best" renders the claims indefinite. Applicant's attention is directed to claim 41, which is not rejected herein, and by contrast with the rejected claims, specifically defines a "best predictor set" as one wherein all of k features have been repeated k times in a row.

The term "highest" in claims 53-54, 58, 60-61 is a relative term which renders the claim indefinite. The term "highest" is not defined by the claim with regard to a "quality" of a set of features, the specification does not provide a standard for ascertaining the

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requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "acceptable" in claims 60-61 is a relative term which renders the claim indefinite. The term "acceptable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. One of skilled in the art would not know what applicant intends as the metes and bounds of an "acceptable threshold" (i.e. what threshold must be achieved?), therefore the claims are indefinite.

Claims 35, 53, and 66 recite a step of "using" a set of predictor features "for predicting said target". Claims 36 and 67 recite "using" a set of predictor features to determine if a target is present in a sample. It is unclear what method steps are intended by the term "using", therefore the claims are indefinite. Applicant has amended the claims to make it clear that the features are to be "used" to predict a target, but it is still unclear what active, positive method steps are intended by the term "using". This rejection may be overcome by reciting language similar to that of claim 57, if such is consistent with applicant's intent.

Claims 46, 58 recite the term "incrementing". Claims 47, 60 recite the term "incremented". Applicant argues that the "plain meaning" of the term, as set forth in Merriam-Webster's dictionary is intended. It is noted, however, that the definition cited by applicant provides several possible meanings (in summary): 1) increasing; 2) one of a series of *regular consecutive* additions; 3) amount of negative or positive change in the value of a set of variables. It was previously acknowledged that an "increment" may be positive or negative. What is not clear is whether *applicant* intends "incrementing" to mean positive changes only (as set forth in meanings (1) and (2) of Merriam-Webster), or intends the term to mean either positive or negative changes (as set forth in meaning

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(3)). Further, it is unclear whether applicant intends the term to mean any amount of change, including irregular amounts, in a series of changes, or intends *regular, consecutive* changes. As applicant's response has not clarified this matter, the examiner maintains that the term renders the claims indefinite.

Claim 68 recites "immunological information". Neither the specification nor the claims define this phrase. In addition, the phrase may have many meanings in the art; e.g. antibody titer, white blood cell count, immunodeficiency status, lymph profile, etc. As it is not clear what meaning applicant intends for this phrase, the claim is indefinite.

Allowable Subject Matter

Claims 40-44 and 51 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 63-65 and 69-70 are allowable.

The following is a statement of reasons for the indication of allowable subject matter and/or allowance: applicant has persuasively argued in a previous office action that the closest prior art does not teach or fairly suggest the claimed method steps. A method which determines a "best" predictor set of features for a target and/or actually predicts a target using such a set is one which recites a practical application and has utility.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571)

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272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

mam

Marjorie A. Moran
6/29/04